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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/581,856

07/13/2007

Vicente R. Tur

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EXAMINER

GAMETT, DANIEL C

ART UNIT

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1647

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/581,856	Applicant(s) TUR ET AL.	
	Examiner DANIEL C. GAMETT	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-72 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The preliminary amendments of 07/13/2007 have been entered in full. Claims 1-72 are under examination.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-19, 41-52, drawn to a β sheet multimeric cytokine whose sequence has been altered so as to improve the free energy of the monomer or of the multimeric complex relative to the wild-type unmutated monomer component so as to be **more stable than the wild-type**, unaltered cytokine protein, and a method of making said cytokine.

Group II, claim(s) 20, 21, 23-34, 53-61, 63-69, 71, and 72 drawn to a β sheet multimeric cytokine with selectivity for a target receptor, in which one or more amino acids in the cytokine that are located in the receptor-binding interface are substituted for replacement residues that include amino acid side-chain conformations that are predicted to fit into the binding interface with the target receptor so as to provide an **increase in binding affinity and selectivity/specificity** of the cytokine protein for that target receptor, a method of making said cytokine, a methods of using said cytokine to treat cancer.

Group III, claim(s) 22, drawn to a β sheet multimeric cytokine with selectivity for two or more target receptors wherein selectivity for a first target receptor is achieved by substituting one or more amino acids in the cytokine for replacement residues so as to **decrease affinity for one or more different target receptors**.

Group IV, claim(s) 35, 37-40, and 62, drawn to a β sheet multimeric cytokine with selectivity for a target receptor whose sequence has been altered so as to be **more stable than the wild-type**, unaltered cytokine protein and whose sequence has been altered so as to provide an **increase in binding affinity and selectivity/specificity** of the cytokine protein for that target receptor, and a method of making said cytokine.

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Group V, claim(s) 36 and 70, drawn to a β sheet multimeric cytokine with selectivity for two or more target receptors whose sequence has been altered so as to be **more stable than the wild-type**, unaltered cytokine protein and wherein selectivity for a first target receptor is achieved by substituting one or more amino acids in the cytokine for replacement residues so as to **decrease affinity for one or more different target receptors**.

3. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I recites the special technical feature, cytokine whose sequence has been altered so as to improve the free energy of the monomer or of the multimeric complex relative to the wild-type unmutated monomer component so as to be **more stable than the wild-type**, unaltered cytokine protein, which is not required by the methods or the products of Groups II or III.

Group II recites the special technical feature, one or more amino acids are substituted for replacement residues so as to provide an **increase in binding affinity and selectivity/specificity** of the cytokine protein, which is not required by the methods or the products of Groups I, III, or V.

Group III recites the special technical feature, substituting one or more amino acids in the cytokine for replacement residues so as to **decrease affinity for one or more different target receptors**, which is not required by the methods or the products of Groups I, II, or IV.

Group IV recites the special technical feature, cytokine with selectivity for a target receptor whose sequence has been altered so as to be **more stable than the wild-type**, unaltered cytokine protein, which is not required by the methods or the products of Groups II or III.

Group IV recites the special technical feature, one or more amino acids are substituted for replacement residues so as to provide an **increase in binding affinity and selectivity/specificity** of the cytokine protein, which is not required by the methods or the products of Groups I, III, or V.

Group V recites the special technical feature, substituting one or more amino acids in the cytokine for replacement residues so as to **decrease affinity for one or more different target receptors**, which is not required by the methods or the products of Groups I, II, or IV.

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4. The following relationships are noted in accordance with the PCT International Search and Preliminary Examination Guidelines, Section 10.30, page 83, Example 10.

Unity exists between Groups I and IV or between Groups II and IV, but not between Groups I and II.

Unity exists between Groups I and V or between Groups III and V, but not between Groups I and III.

5. Consequently:

a. If Applicant elects Group I, Applicant may also elect Group IV or Group V, but not both of Groups IV and V.

b. If Applicant elects Group II, Applicant may also elect Group IV.

c. If Applicant elects Group III, Applicant may also elect Group V.

d. If Applicant elects Group IV, Applicant may also elect Group I or Group II, but not both of Groups I and II.

e. If Applicant elects Group V, Applicant may also elect Group I or Group III, but not both of Groups I and III.

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

7. The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

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8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C. Gamett, PhD., whose telephone number is (571)272-1853. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571 272 0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel C Gamett/
Examiner, Art Unit 1647